

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

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(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PH/8395INT	FOR FURTHER ACTION	
See Form PCT/IPEA/416		
International application No. PCT/GB2004/001714	International filing date (day/month/year) 16.04.2004	Priority date (day/month/year) 16.04.2003
International Patent Classification (IPC) or national classification and IPC A61M15/00		
<p>Applicant LOUGHBOROUGH UNIVERSITY ENTERPRISES LIMITED et al.</p> <p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 7 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> <i>(sent to the applicant and to the International Bureau)</i> a total of sheets, as follows:</p> <ul style="list-style-type: none"> <input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report (Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. <p>b. <input type="checkbox"/> <i>(sent to the International Bureau only)</i> a total of (indicate type and number of electronic carrier(s)), containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> <p>4. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Box No. I Basis of the opinion <input type="checkbox"/> Box No. II Priority <input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input type="checkbox"/> Box No. VII Certain defects in the international application <input type="checkbox"/> Box No. VIII Certain observations on the international application 		
Date of submission of the demand 15.11.2004	Date of completion of this report 03.05.2005	
Name and mailing address of the international preliminary examining authority: European Patent Office. D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	<p>Authorized Officer Rodríguez Cossío, J Telephone No. +49 89 2399-8662</p> 	

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Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
 - This report is based on translations from the original language into the following language, which is the language of a translation furnished for the purposes of:
 - international search (under Rules 12.3 and 23.1(b))
 - publication of the international application (under Rule 12.4)
 - international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

Description, Pages

1-14 as originally filed

Claims, Numbers

1-54 as originally filed

Drawings, Sheets

1/3-3/3 as originally filed

- a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. The amendments have resulted in the cancellation of:
 - the description, pages
 - the claims, Nos.
 - the drawings, sheets/figs
 - the sequence listing (*specify*):
 - any table(s) related to sequence listing (*specify*):
4. This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
 - the description, pages
 - the claims, Nos.
 - the drawings, sheets/figs
 - the sequence listing (*specify*):
 - any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:
 - the entire international application,
 - claims Nos. 1-19,39-44,52,53,54
 - because:
 - the said international application, or the said claims Nos. 1-19,39-44,52 relate to the following subject matter which does not require an international preliminary examination (specify):
see separate sheet
 - the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 53,54 are so unclear that no meaningful opinion could be formed (*specify*):
see separate sheet
 - the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
 - no international search report has been established for the said claims Nos. 1-19,39-44,52,53,54
 - the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
 - the written form has not been furnished does not comply with the standard
 - the computer readable form has not been furnished does not comply with the standard
 - the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
 - See separate sheet for further details

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	20-38,45-51
	No: Claims	
Inventive step (IS)	Yes: Claims	20-38,45-51
	No: Claims	
Industrial applicability (IA)	Yes: Claims	20-38,45-51
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Re Item III

1. No opinion under Article 33(1) PCT will be establish for the subject-matter of claims 1-19, 39-44 and 52-54 since no Search Report has been established (Rule 39.1(iv) PCT) for these claims (Article 34(4)(a)(i) and (b) and Rule 70.2(d) PCT).
2. Claims 19, 39-44 and 52 relate to a subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT, namely to a method for treatment of the human body by therapy, since the method of assessing the effectiveness of pulmonary drug delivery to which they all refer has to be carried out during the drug therapy. Consequently, no opinion under Article 33(1) PCT will be formulated with respect to the subject-matter of these claims (Article 34(4)(a)(i) and (b) and Rule 67.1(iv) PCT).
- 2.1 The method explicitly includes the steps of "**providing a drug in an air flow**" in claim 1, "**release of the drug from a drug delivery device**" in claim 4, or "**the air flow is provided by a person's breath in-take**" in claim 5.
- 2.2 As additional comments, it is noted that even if some claims do not explicitly mention the human body and the air flow might be produced by an apparatus, the method would **also** encompass the case where the air flow is that produced by the human body, in view of the context of the invention, in the light of the description. In the present case, moreover, claim 5, which depends back on claim 1 explicitly states the "**the air flow is provided by a person's breath in-take**".

The method of the claims cannot be considered to be simply a method of "measuring a characteristic of the human body", since the "effectiveness of a pulmonary drug delivery" is not a characteristic of the human body but it rather, at least also, depends on the drug characteristics and the way of administration. Thus the method implies that a drug must be administered to the patient, i.e. it relates to a method of therapy to be practised on the human body. This is even explicitly stated in the claims as showed above.

Even if the method could be seen as a "method of testing", there is still a drug

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administration to a patient involved in the method, so it is de facto a therapeutical treatment practised on the human body.

3. Claim 53 tries to define the scope of protection by referring to the accompanying drawings only. This, and the obscure definition of claim 54, do not allow the reader to determine the subject-matter to which these claims refer (Article 6 PCT). Consequently, no opinion under Article 33(1) PCT will be formulated with respect to the subject-matter of these claims (Article 34(4)(a)(ii) and (b) PCT).

Re Item V

Reference is made to the following documents:

D1: EP-A-0 824 023 (MICROFLOW ENG SA) 18 February 1998 (1998-02-18)

1. The document **D1** is regarded as being the closest prior art to the subject-matter of claim 20, and shows (the references in parentheses applying to this document):
A measurement device for assessing the effectiveness of pulmonary drug delivery (abstract), comprising:
a conduit (Fig. 4) through which air carrying a cloud of drug particles can flow during drug delivery;
The subject-matter of claim 20 differs from this known device in that it further comprises:
a radiation source for providing radiation into the conduit;
a radiation detector for detecting radiation from the conduit over a period of time as a measurement profile; and
a processor operable to quantify one or more characteristics of the shape of a measurement profile and to produce an indication of the effectiveness of pulmonary drug delivery based upon the quantified characteristics.

The subject-matter of claim 1 is therefore new (Article 33(2) PCT).

The problem to be solved by the present invention may be regarded as how to improve the control of the effectiveness of the drug delivery.

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The solution to this problem proposed in claim 20 of the present application is considered as involving an inventive step (Article 33(3) PCT) since the radiation source and detector allow for the acquisition in real time during drug delivery of a profile from which one or more characteristics of the cloud of drug particles can be quantified.

Claims 21-38 are dependent on claim 20 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

The same applies to the subject-matter of independent claims 45 and 46 and dependents 47-51 which, however, for the sake of conciseness and clarity should be drafted as dependent on claim 20.